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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,501	06/01/2001	Tetsuko Takabe	026350-053	7822

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 01/02/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,501

Applicant(s)

TAKABE, TETSUKO

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 7-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-6 is/are rejected.
- 7) ☒ Claim(s) 5-6 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 3-6, in Paper No. 10 is acknowledged.

The petition under 37 CFR 1.84(a)(2) filed 01 June 2001 regarding color photographs has been GRANTED.

Specification

The title is objected to because the words "transgenic" and "exhibiting" are misspelled.

The specification is objected to because Figure 5 is labeled as Figure 5 A and Figure 5 B, but subparts A and B are not described in the brief description of the drawings. Figure 7 is also so labeled but not so described.

Claim Objections

Claims 3-4 are objected to for depending upon non-elected claims.

Claim 5 is objected to because of the following informalities: the article "the" is omitted between "of" and "following" in line 1. Appropriate correction is required.

Claim 5 is objected to because "condition" in part (e) should be "conditions". Appropriate correction is required.

Claim 6 is objected to because "of" should be omitted between "70%" and "homology". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a gene encoding the polypeptide according to claim 1, a gene encoding the polypeptide according to claim 2, a gene consisting of a base sequence of SEQ ID NO:2, a gene in which the base sequence of SEQ ID NO:2 has been deleted, added to, or partially substituted, a gene in which the base sequence hybridizes with SEQ ID NO:2 under stringent conditions, and a gene consisting of a base sequence having at least 70% homology to SEQ ID NO:2.

The specification describes a cDNA of SEQ ID NO:2 encoding the amino acid sequence set forth in SEQ ID NO:1 (sequence listing). The specification also describes the amino acid sequence set forth in SEQ ID NO:1 as having homology to known peroxisomal ascorbate peroxidases (page 11). The specification does not describe the structure of any nucleotide sequence encoding any amino acid sequence other than SEQ ID NO:1. The specification does not describe the structure of any nucleotide sequence derived from barley and induced by high-temperature stress in which the base sequence of SEQ ID NO:2 has been deleted, added to, or partially substituted and which encodes a functional protein. The specification does not describe

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the structure of any nucleotide sequence derived from barley and induced by high-temperature stress which hybridizes to SEQ ID NO:2 and which encodes a functional protein. The specification does not describe the structure of any nucleotide sequence derived from barley and induced by high-temperature stress which has at least 70% homology to SEQ ID NO:2 and which encodes a functional protein.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed product, any method of using it would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No.4/ Friday January 5, 2001/Notices: pp. 1099-1111).

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Claims 3-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid of SEQ ID NO:2 encoding a polypeptide of SEQ ID NO:1 that confers heat stress tolerance to a plant, does not reasonably provide enablement for other isolated nucleic acids encoding other polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a gene encoding the polypeptide according to claim 1, a gene encoding the polypeptide according to claim 2, a gene consisting of a base sequence of SEQ ID NO:2, a gene in which the base sequence of SEQ ID NO:2 has been deleted, added to, or partially substituted, a gene in which the base sequence hybridizes with SEQ ID NO:2 under stringent conditions, and a gene consisting of a base sequence having at least 70% homology to SEQ ID NO:2.

The specification discloses the isolation from salt stressed barley leaves of a cDNA of SEQ ID NO:2 encoding the amino acid sequence set forth in SEQ ID NO:1 (pages 8-11). The specification also discloses that SEQ ID NO:2 hybridizes to an mRNA that increases under salt and heat stress conditions (page 12), and that the amino acid sequence set forth in SEQ ID NO:1 has homology known peroxisomal ascorbate peroxidases (page 11). The specification also discloses that plants transformed with SEQ ID NO:2 are more tolerant to heat stress than nontransformed control plants (page 14 and Figures 8 and 9). The specification does not disclose how to make specific deletions, additions or substitutions in SEQ ID NO:2 such that the function of the encoded polypeptide would not be adversely affected. The specification does not disclose the isolation of sequences that hybridize with SEQ ID NO:2 under stringent conditions and that

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encode a functional polypeptide. The specification does not disclose the isolation of sequences that have at least 70% homology to SEQ ID NO:2 and that encode a functional polypeptide.

Guidance for making and using the claimed invention is necessary for enablement because it is unpredictable whether a base sequence of SEQ ID NO:2 that has been deleted, added to, or partially substituted will encode a functional polypeptide. It is also unpredictable whether a base sequence that hybridizes with SEQ ID NO:2 under stringent conditions or has at least 70% homology to SEQ ID NO:2 will encode a functional polypeptide. A change in as few as one nucleotide in a base sequence, such as would occur by deletion, addition, substitution, hybridization or as a consequence of percent homology, can alter the amino acid sequence of the polypeptide it encodes, and a change in as few as one amino acid in a polypeptide can alter or eliminate its function. For example, Rhoads et al. (J. Biol. Chem., November 1998, Vol. 273, No. 46, pages 30750-30756) teach that mutation of Cys-128 to Ala in an *Arabidopsis* alternative oxidase caused a pronounced overall increase in enzyme activity relative to the wild-type in the presence or absence of pyruvate (page 30753 Figure 3). Mutation of Cys-78 to Ala in the same *Arabidopsis* alternative oxidase resulted in a minimally active enzyme that showed no response to added pyruvate (page 30753 Figure 3).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, it would require undue experimentation for one skilled in the art to determine which of the claimed base sequences would encode a functional and therefore useful polypeptide.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 3-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-6 are indefinite in the recitation of "a gene". The word gene implies DNA existing in nature that includes coding regions and noncoding regions, such as enhancers, promoters, and introns. The nucleic acid of SEQ ID NO:2 appears to be a cDNA sequence and thus would not constitute a gene. It is suggested that the claims be amended to recite "an isolated polynucleotide" or "an isolated nucleic acid".

Claim 5 is indefinite in the recitation of "under stringent condition". It is unclear what conditions would yield the claimed base sequence, as those skilled in the art define stringency conditions differently. It is suggested that the claims be amended to recite specific hybridization conditions.

Claim 5 is indefinite in the recitation of "(c)", "(d)", and "(e)", as claim 5 lacks subparts (a) and (b). It is suggested that "(c)", "(d)", and "(e)" be amended to "(a)", "(b)", and "(c)" if subparts (a) and (b) were not unintentionally omitted from the claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a gene.

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Claims 3-6, as written, do not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated nucleic acid" or "Purified nucleic acid". See MPEP 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Bunkelmann et al. (GenBank Accession No. U37060, 23 April 1997, and SPTREMBL Accession No. Q38780, 01 November 1996).

The claims are drawn to a gene encoding the polypeptide according to claim 1, a gene encoding the polypeptide according to claim 2, a gene in which the base sequence of SEQ ID NO:2 has been deleted, added to, or partially substituted, a gene in which the base sequence hybridizes with SEQ ID NO:2 under stringent conditions, and a gene consisting of a base sequence having at least 70% homology to SEQ ID NO:2, said sequence being induced by high-temperature stress and being derived from barley.

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Bunkelmann et al. teach an isolated nucleic acid having 72.1 % sequence similarity to SEQ ID NO:2 and encoding a polypeptide having 80.4% sequence similarity to SEQ ID NO:1, said sequence having inherent deletions, additions or substitutions as well as the ability to hybridize to SEQ ID NO:2 under conditions of unspecified stringency. While the sequence taught by Bunkelmann et al. was not derived from barley, and Bunkelmann et al. do not explicitly teach induction of their sequence by high-temperature stress, the limitations "derived from barley" and "induced by high-temperature stress" do not impose any specific structural limitations on the claimed base sequence.

Remarks

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
December 26, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

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Acting SPE